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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,798	11/25/2003	Christos J. Petropoulos	011068-072-999	9090
20583	7590	03/18/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			MOSHER, MARY	
			ART UNIT	PAPER NUMBER

1648

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

4/c

## Office Action Summary

Application No.

10/723,798

Applicant(s)

PETROPOULOS, CHRISTOS J.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/9/2004.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

Claim 13 and 38 are objected to because of the following informalities: the claims are missing "is an" after "avian cell". Appropriate correction is required.

Claim 55 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend from other claims only as alternatives. The claim requires step (b) to be done both according to claim 50 (because that is required by the parent claim) and according to claim 32. See MPEP § 608.01(n).

### ***Claim Rejections - 35 USC § 112***

Claims 1-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims in this application all require a hepadnavirus virion to be made infectious to cells where it normally is noninfectious (e.g. cultured cells), by incorporation of part or all of a foamy virus envelope protein. This method of changing the host range of a virus, by incorporating a foreign virus external protein, is often termed pseudotyping. The prior art recognizes that foamy virus envelope proteins can be used to pseudotype another retrovirus (see Lindemann et al 6,150,138) and VSV (see Hill et al, J. Gen. Virol. 80:2003-2009, 1999). However, the examiner was unable to find any art (prior or later) indicating successful pseudotyping of hepatitis B virus (HBV) by the envelope protein of any virus other than another species of HBV. Eastman et al (not prior art) indicates that it was known in the art that HBV and foamy

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viruses both require expression of the envelope protein for budding of intracellular capsids from the cell, and indicates that gag-env interactions are essential to drive budding of infectious particles. Since the prior art does not permit one to predict whether or not the HBV and FV gag and env proteins are able to interact with the heterologous protein, one skilled in the HBV art would have reason to doubt unsupported assertions regarding pseudotyping of HBV. While the specification contains detailed discussion of methods to use, the specification contains no working example where cell-culture-infectious HBV particles were actually produced. Considering the state of the art, the lack of a working example, and the unpredictability of success in producing an infectious HBV pseudotype using an envelope protein from a distinct virus family, it is concluded that undue experimentation would be required to make and use the invention as claimed. This rejection could be obviated by a showing of evidence that the methods taught in the specification actually do produce cell-culture-infectious hepadnavirus.

### ***Conclusion***

Claims 1-55 are free of the art. Lindemann et al 6,150,138 broadly teaches production of pseudotyped virus particles with foamy virus envelope protein, but does not teach or suggest hepadnaviruses as a species to pseudotype. Capon et al teaches screening methods for testing drug resistance in hepatitis B virus, but does not teach or suggest use of a foamy virus envelope protein. Hill et al teaches a pseudotyped VSV with foamy virus envelope protein, but does not teach or suggest hepadnaviruses. Ishikawa et al, PNAS 92:6259-6263, 1995, is cited as of interest in teaching pseudotyping between two species of avian HBV, and Chouteau et al (Journal of

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Virology 75:11565-11572, December 2001, not available as prior art) is cited as of interest in teaching pseudotyping between two species of primate HBV.


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 15, 2005

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800-1600**